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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/484,542	06/07/1995	MARK L. BRADER	X-10097	4610

7590 10/24/2002

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LILLY CORPORATE CENTER
INDIANAPOLIS, IN 46285

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/24/2002

36

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/484,542

Applicant(s)

BRADER ET AL.

Examiner

Marianne P. Allen

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-32, 57, 58 and 60-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32, 57, 58 and 60-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 33. 6) ☐ Other: _____

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DETAILED ACTION

Claims 33-35, 56, and 59 have been cancelled. Claims 61-64 have been newly added.

Claims 27-32, 47-48, and 60-64 are under consideration by the examiner.

The examiner acknowledges applicant's clarification on page 3, section III, of the response. The response was submitted 10/9/01 and received by the Office 10/12/01.

Information Disclosure Statement

The supplemental IDS submitted 11/20/02 is noted. It was matched with the application subsequent to mailing of the Office action mailed 1/11/02. The initialed Form 1449 is attached to this correspondence.

Claim Rejections - 35 USC § 112

Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 lacks antecedent basis in claim 63 for the term "preservative." Note that claim 63 uses the term "compound."

Claim Rejections - 35 USC § 102

The declaration filed on 21 August 1998 under 37 CFR 1.131 was sufficient to overcome the Baker et al. (U.S. Patent No. 5,693,609) reference with respect to claims 27-35. (See discussion in Paper No. 17. Notably zinc is not recited as a limitation in the patent claims and as such a 1.131 declaration is permissible for the present claims.)

The examiner again notes applicant's prior argument that the instant specification narrowly defines "insulin" to be directed to normal or naturally occurring insulin from beef, pork,

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and human and does not encompass acylated analogs and that the teachings of the '609 patent are directed to acylated analogs and not acylated normal or naturally occurring insulin from beef, pork, and human.

For all of these reasons, Baker et al. has not been applied to new claims 61-64.

Claims 27-32, 57-58, and 60-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Havelund et al. (U.S. Patent No. 5,750,497) or Havelund et al. (U.S. Patent No. 6,011,007).

The '007 patent is a continuation-in-part of the '497 patent and both sets of claims are directed to overlapping subject matter that anticipates the instant claims.

Havelund et al. ('497) discloses and claims compositions comprising fatty acid acylated insulin and zinc. The claims encompass normal or naturally occurring forms of insulin as defined by the instant specification as well as analogs. The lysine at position B29 is acylated. The compositions may be aqueous and contain a preservative. The aqueous composition may be between pH 6.5 and 8.5. (See claims.) The specification indicates that the preservative may be phenol or m-cresol. (See column 15, lines 53-55, and claims.) An isotonic agent such as glycerol may be included. (See column 15, line 19, and claims.) N-palmitoyl Lys B²⁹ insulin is disclosed. (See Table 2.) Havelund et al. ('497) does not appear to disclose the amount of zinc present in mole/mole terms; however, absent evidence to the contrary, it appears that these limitations would be met. Havelund et al. ('497) does not appear to disclose the concentration of the phenolic compound present; however, absent evidence to the contrary, it appears that these limitations would be met. Applicant is reminded that the Patent Office does not have laboratory facilities to make such determinations. Havelund et al. ('007) discloses the same subject matter.

Applicant is reminded that any reply must appear throughout to be a bona fide attempt to advance the application to final action. Applicant has requested that this ground of rejection be held in abeyance for at least the last two responses. **Should applicant fail to substantively respond to this art rejection in their next response, the submission will be held to be non-responsive.**

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

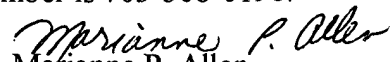
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
October 23, 2002